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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,680	12/04/2003	Cheryl Baird	02-1181-A	8461
20306	7590	06/19/2007		
MCDONNELL BOEHNNEN HULBERT & BERGHOFF LLP			EXAMINER	
300 S. WACKER DRIVE			CHIN, CHRISTOPHER L	
32ND FLOOR			ART UNIT	PAPER NUMBER
CHICAGO, IL 60606			1641	
			MAIL DATE	DELIVERY MODE
			06/19/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/727,680	<b>Applicant(s)</b> BAIRD ET AL.	
	<b>Examiner</b> Christopher L. Chin	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 15-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 and 11-14 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. This application contains claims 1-8 and 15-22 drawn to an invention nonelected with traverse in the reply filed on 11/13/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Rejections - 35 USC § 112***

2. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is vague. The claimed biosensor appears to be for detection of an analyte. The one or more specific binding substances immobilized on the first portion recited in claim 9 would appear to be for specific binding and detection of an analyte. However, detection of analyte would not be possible if the specific binding substances are bound to their specific binding partners, as recited in claim 13.

Claim 13 is not clear as to what is being claimed. Applicants assert that when claim 13 is read in light of the specification, the claim is clear. While the claims must be read in light of the specification, the claims must also clearly define and set forth the invention. As noted above, the claim is not clear as it appears that the claimed biosensor is for detection of an analyte but detection of the analyte is not possible if the binding substances are already blocked by their specific binding partners.

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Applicants also assert that claim 13 reads on the result of sample contacting the biosensor of claim 9 where specific binding partner in the sample has bound to the specific binding substance on the biosensor. This suggests that claim 13 reads on a "used" biosensor. If Applicants intend to claim a "used" biosensor, then claim 13 raises the possibility of a rejection under 35 USC 101 for lack of utility. A "used" biosensor would not appear to have utility if it cannot detect an analyte.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 9, 11, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudigier et al (US Patent 5,738,825) in view of Godfrey (US Patent 4,992,385) for the reasons of record.

In response to this rejection Applicants argue that the cited references do not teach each and every element of the claims and there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings.

Applicant's arguments have been considered but are not convincing. Contrary to Applicant's arguments, the combination of Rudigier and Godfrey do in fact teach all of

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the elements recited in the rejected claims. The device of Rudigier teaches one or more liquid holding vessels with an optical biosensor in each of the vessels, wherein specific binding substances are immobilized on the optical biosensor. Godfrey teaches an optical biosensor similar to those used in the vessels of Rudigier but also includes a standard region devoid of any specific binding substances. Detection of analyte in Godfrey is done by comparing results from the testing regions that contain specific binding substances with results from the standard region. It would have been obvious to incorporate the standard region, as taught by Godfrey, into each well of Rudigier's device because it provides for qualitative analysis of analytes, which is the purpose of Rudigier's device. Furthermore, as noted by Applicants, Rudigier appreciated the use of references in column 3, lines 39-50, for comparison to assay results. Godfrey provides an alternative reference that does not require the use of a carrier fluid as taught by Rudigier.

With respect to Applicant's argument concerning the use of at least two test droplets in two distinct regions, as taught by Godfrey, Applicant's would appear to be arguing Godfrey separately without considering Rudigier. The combination of Rudigier and Godfrey would have the test regions and standard regions in the same well. The need for at least two test droplets in two distinct regions would be obviated since the test region and standard region would be in the same well and both regions contacted by the same sample.

***Allowable Subject Matter***

5. Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

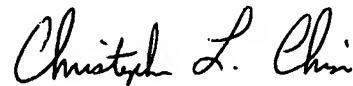
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christopher L. Chin  
Primary Examiner  
Art Unit 1641

6/4/07